25. (new claim) The composition of Claim 24 wherein said water soluble carrier is polyethylene glycol (PEG).

26. (new claim) A pharmaceutical composition comprising a dispersion of a combination of (2S,3S,5S)-5-(N-(N-((N-methyl-N-((2-isopropyl-4-thiazolyl)methyl)amino)carbonyl)-L-valinyl)amino)-2-(N-((5-thiazolyl)methoxy-carbonyl)-amino)-1,6-diphenyl-3-hydroxyhexane (ritonavir) and (2S,3S,5S)-2-(2,6Dimethylphenoxyacetyl)amino-3-hydroxy-5-[2S-(l-tetrahydro-pyrimid-2-onyl)-3-methyl butanoyl] amino-1,6-diphenylhexane (ABT-378) in a water soluble carrier wherein the ritonavir and ABT-378 are in amorphous form in the dispersion.

27. (new claim) The composition of Claim 26 wherein said water soluble carrier is polyethylene glycol (PEG).

28. (new claim) A pharmaceutical composition comprising a dispersion of nelfinavir in a water soluble carrier wherein the nelfinavir is in amorphous form in the dispersion.

29. (new claim) The composition of Claim 28 wherein said water soluble carrier is polyethylene glycol (PEG). - -

REMARKS

This is a response to the Office Action dated February 20, 2002, the period for response to which has been extended three months from May 20, 2002 to August 20, 2002.

In the Office Action, the Examiner has (1) objected to the claim for priority under 35 U.S.C. 119(e), (2) rejected Claims 3-5 and 12-18 under 35 U.S.C. 112, second paragraph, (3) objected to Claims 5, 6, 8, 15, 20 and 21 for certain informalities, (4) rejected Claims 1-5, 9, 11-13 and 17-20 under 35 U.S.C. 102(b) and (5) rejected Claims 1-8, 10 and 12-21 under 35 U.S.C. 103(a).

In this response, Applicants traverse the objections and rejections and respectfully request reconsideration of the claims as amended herein.

In addition, Applicants submit herewith a Supplemental Information Disclosure Statement.

Supplemental Information Disclosure Statement

It has come to Applicants' attention that Applicants' file copy of previously cited reference Aungst, et al., International Journal of Pharmaceutics **156** 79-88 (1997) only contains copies of every other page. In case this is also true of the copy provided to the Examiner with Applicants' Information Disclosure Statement and Form PTO1449 submitted on November 10, 2000, Applicants submit herewith a complete copy of this reference, along with a new Form PTO1449 listing this reference.

Applicants respectfully request that the Examiner acknowledge receiving, considering and making of record this reference by initialing and dating a copy of this new Form PTO1449 and returning the initialed and dated Form PTO1449 to Applicants.

Objection to Priority Claim

The Examiner has objected to the claim for priority under 35 U.S.C. 119(e). Applicants thank the Examiner for bringing to their attention the obvious typographical error in the priority claim. The priority claim has been corrected by amendment herein. Therefore, the Examiner is respectfully requested to withdraw this objection.

Section 112 Rejection

The Examiner has rejected Claims 3-5 and 12-18 under 35 U.S.C. 112, second paragraph. Claims 3-4 and 12-18 have been cancelled by amendment herein, without prejudice to the patentability thereof. Claim 5 has been amended herein to include standard Markush terminology. Therefore, the Examiner is respectfully requested to reconsider and withdraw the Section 112 rejection.

Objections to Chemical Nomenclature Informalities

The Examiner has objected to Claims 5, 6, 8, 15, 20 and 21 because of certain informalities in the chemical nomenclature therein. Applicants thank the Examiner for bringing to their attention the obvious typographical errors in the chemical nomenclature in these claims. Applicants have made the requested corrections by amendment herein. The corresponding corrections have also been made to the specification by amendment herein. Therefore, the Examiner is respectfully requested to withdraw this objection.

Section 102 Rejections

(a) The Examiner has rejected Claims 1-5 and 11 under 35 U.S.C. 102(b) as being anticipated by Aungst, et al. (Int. J. Pharmaceutics **156** 79-88 (1997)). Applicants respectfully assert that the Aungst, et al. reference does not disclose the presently claimed invention. While the Aungst, et al. reference does mention a solid dispersion of DMP323 in PEG, this dispersion does not comprise DMP323 in amorphous form. Furthermore, the oral bioavailability of this solid dispersion in dogs was less than 0.5% and this dispersion was characterized as being unsuccessful. See Section 3.3 and Table 2 (pages 83-84).

In view of the above, the Examiner is respectfully requested to reconsider and withdraw this Section 102 rejection.

(b) The Examiner has rejected Claims 1-5, 7, 9, 11-13, 17 and 18 under 35 U.S.C. 102(b) as being anticipated by Aungst, et al. (B.T. Gattetosse **87** 49-54 (1994)). Applicants respectfully assert that this Aungst, et al. reference does not disclose the presently claimed invention. The disclosure of this Aungst, et al. reference is very similar to that mentioned in (a) above. The disclosed PEG solid dispersion of DMP323 does not comprise DMP323 in amorphous form. Furthermore, because of the very low oral bioavailability of this solid dispersion in dogs, Aungst states, "Based on the very poor performance of these solid dispersions, this approach was not pursued further" (see page 51, 1st column).

In view of the above, the Examiner is respectfully requested to reconsider and withdraw this Section 102 rejection.

(c) The Examiner has rejected Claims 1-6, 9, 11, 19 and 20 under 35 U.S.C. 102(b) as being anticipated by Al-Razzak, et al. (U.S. Patent No. 5,610,193). Applicants respectfully assert that the Al-Razzak, et al. reference does not disclose the presently claimed invention. While the Al-Razzak, et al. reference does mention a solid dispersion of ritonavir in PEG, this dispersion does not comprise ritaonvir in amorphous form. Furthermore, the oral bioavailability of this solid dispersion in dogs was less than 5%. See column 3, lines 32-33.

In view of the above, the Examiner is respectfully requested to reconsider and withdraw this Section 102 rejection.

Section 103 Rejections

The Examiner has (a) rejected Claim 19 under 35 U.S.C. 103(a) as being obvious over Aungst, et al. (Int. J. Pharmaceutics **156** 79-88 (1997)), (b) rejected Claims 10 and 14 under 35 U.S.C. 103(a) as being obvious over Aungst, et al. (B.T. Gattetosse **87** 49-54 (1994)) and further in view of Sherman (WO96/23499), (c) rejected Claim 19 under 35 U.S.C. 103(a) as being obvious over Aungst, et al. (B.T. Gattetosse **87** 49-54 (1994)), (d) rejected Claims 12, 13, 15, 17 and 18 under 35 U.S.C. 103(a) as being obvious over Al-Razzak, et al. (U.S. Patent No. 5,610,193), (e) rejected Claims 5-8, 15, 16, 20 and 21under 35 U.S.C. 103(a) as being obvious over Al-Razzak, et al. (U.S. Patent No. 5,610,193) and further in view of Sham, et al. (U.S. Patent No. 5,914,332) and (f) rejected Claims 1-6, 10, 19 and 20 under 35 U.S.C. 103(a) as being

obvious over Sherman (WO96/23499) in view of Aungst, et al. (B.T. Gattetosse 87 49-54 (1994)) or Al-Razzak, et al. (U.S. Patent No. 5,610,193).

Applicants respectfully traverse all of these Section 103 rejections. Firstly, Applicants have cancelled Claims 12-18 by amendment herein, without prejudice to the patentability thereof. Therefore, no further comment will be made about Section 103 rejections of these claims.

Secondly, Applicants assert that none of the cited references, taken alone or in combination, either disclose or suggest the claimed invention. Both of the Aungst references teach away from the use of a solid dispersion of an HIV protease inhibitor. The Al-Razzak reference teaches that a solid dispersion formulation of ritonavir does not provide good oral bioavailability. The Sherman reference does not teach or suggest a solid dispersion formulation of an HIV protease inhibitor.

In view of the above, Applicants assert that none of the cited references, either taken alone or in combination, teach or suggest the presently claimed invention. Therefore, the Examiner is respectfully requested to reconsider and withdraw the Section 103 rejections.

Action Requested

In view of all of the above, reconsideration and allowance of Claims 1-2, 5-11 and 19-21 (as amended) and Claims 22-29 (newly added) is respectfully requested.

Respectfully submitted,
J. Fort, et al.

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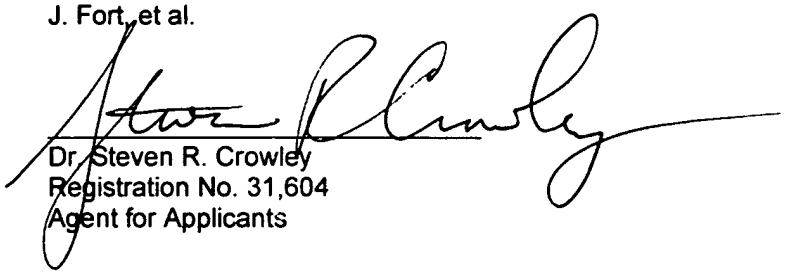

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